K120080

510(k) Summary of Safety and Effectiveness

MAY 25 2012

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Submitter Name:	SHASER Inc.
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Contact Person:	Daniel L. Roth
Phone Number:	(781)995-2246
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Date Prepared:	December, 2011
Device Trade Name:	Shaser HRS2 Hair Removal System
Device Common Name:	Light-based Hair Removal System
Classification Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology, product code ONF
Predicate devices:	Shaser IPL Hair Removal System, K103560 Home Skinovations Silk'n Flash N Go K103184
Reason for submission:	Expanded use indication

Device Description:
The SHASER HRS2 Hair Removal System is a personal, light-based, hair reduction system intended to be sold over-the-counter directly to the end user. The device provides permanent hair reduction as defined below using Intense Pulsed Light (IPL) technology.

The SHASER HRS2 Hair Removal System consists of a powered base unit and a tethered hand piece from which the IPL flashes are delivered to the patient's skin. The system will be sold with light cartridges, cleaning cloth, and user's manual.

Intended Use:
The SHASER HRS2 Hair Removal System is an over-the-counter device intended for removal of unwanted hair. It is also intended for permanent reduction in unwanted hair. Permanent hair reduction is defined as the long-term stable reduction in the number of hairs re-growing when measured at 6, 9, and12 months after the completion of a treatment regimen.

Performance Data
The device complies with the following U.S. Food and Drug Administration performance standards: 21 CFR § 1040.10 & 1040.11. A clinical.trial was conducted to demonstrate the safety and effectiveness of the SHASER HRS2 Hair Removal System for over the counter use for permanent reduction in hair regrowth defined as a long-term, stable reduction in hair counts following a treatment regime. In a clinical trial, test sites including arm, leg, chest, abdomen, bikini line and underarms were treated 3 times at 2 week intervals on a population of approximately 50% female and 50% male subjects from diverse demographic sub-groups. Hair counts were taken before treatment and 3, 6, and 12 months following the final treatment. The results showed an average reduction of 37%, 48%, and 66% at each respective end point.

Substantial Equivalence
Technological Characteristics and Comparison to Predicate Device(s):
The SHASER HRS2 Hair Removal System is substantially equivalent to the Shaser IPL Hair Removal System K103560 and the Home Skinovations Silk'n Flash N Go K103184

The SHASER HRS2 Hair Removal System has similar intended use and indications, and same technological characteristics, and principles of operation as the predicate devices. Any minor differences between the SHASER HRS2 Hair Removal System and its predicate devices raise no new questions of safety or effectiveness nor change the device's intended therapeutic effect in comparison to its predicates. Performance data demonstrate that SHASER HRS2 Hair Removal System is as safe and effective as its predicate devices for the stated indications. Thus, the SHASER HRS2 Hair Removal System is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAY 2 5 2012

Shaser, Incorporated
% The CRO Group, Incorporated
Mr. Glen Emelock
Senior Partner
32 Harrison Street
Melrose, Massachusetts 02176

Re: K120080
Trade/Device Name: SHASER HRS2 Hair Removal System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: ONF
Dated: March 06, 2012
Received: March 07, 2012

Dear Mr. Glen Emelock:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K120080

Device Name: SHASER HRS2 Hair Removal System

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Permanent hair reduction is defined as the long-term stable reduction in the number of hairs re-growing when measured at 6, 9, and12 months after the completion of a treatment regimen.

Prescription Use _____ AND/OR Over-The-Counter Use ___X___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for mxm
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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